K013485
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JAN 17 2002

EXHIBIT # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

Microlife Corporation
9F, 431 Rui Guang Road
Nei Hu,
Taipei 114
Taiwan, Republic of China

Contact:

Mr. Laurence Yang

Date Summary Prepared: October 17, 2001

2. **Name of the Device:**

Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1, with Optional Thermal Printer, Model PR 1KA1.

3. **Predicate Device Information:**

The Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1 is substantially equivalent to the Microlife Automatic Blood Pressure Monitor, Model BP-2BHO, K# 970211.

4. **Device Description:**

The Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1 is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse

rate, which is a well - known technique in the market called the "oscillometric method".

An optional printer is included as an accessory which can be sold separately in a separate box with the printer user manual.

5. **Intended Use:**

The Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1, with Optional Thermal Printer, Model PR 1KA1, is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. This device can be used in connection with the Microlife Thermal Printer.

6. **Comparison to Predicate Devices:**

Both devices use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. An upper arm cuff is inflated automatically; deflate rate is controlled by a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. Each device uses a similar capacitance-type pressure sensor to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Once the reading is determined each unit operates a solenoid valve to release the pressure to zero. Our Blood Pressure Monitor, Model BP-3BTO-1, differs from the predicate device in the fuzzy logic inflation.

The interface between the sensor and the microprocessor determines the system's accuracy. For our Pressure Monitor, Model BP-3BTO-1, the software is capable of a split slope resolution to improve accuracy over the entire range. Since the range is "split" into the three sections (0 to 100mmHg) (100 to 200mmHg) (200 to 300mmHg) error due to nonlinearity is reduced by the ability to adjunct the slope to best fit the output curve. A nonlinearity of 1% is reduced to 0.33% by splitting the span into three separated linear relations. This way the sensor is matched to the software by using a series of jumpers that profile the slopes to the output of the sensor.

The Microlife Automatic Blood Pressure Monitor, Model BP-3BTO-1, has field calibration access; this model is initiated by the following steps: (a) Remove one battery from compartment first, (b) When inserting back the battery, press and hold "I/O" key, and don't release it until the battery is inserted well.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Automatic Blood Pressure Monitor, Model BP-3BTO-1 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. General Functions Test
b. Reliability Test - Operation Conditions
c. Reliability Test - Drop Testing
d. Reliability Test - Storage
e. Reliability Test - Vibrating Testing
f. EMC Test
g. IEC 60601-1 Safety Test
h. Blood Pressure Monitor Printer Port Function Test Report
i. Thermal Printer Software Validation Report
j. EMC Test Report - Blood Pressure Monitor - Connected with Thermal Printer

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1 tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10-1992 "National Standard for Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The BP-3BTO-1 met all relevant requirements of this standard.

9. Conclusions:

We have demonstrated that the Microlife Automatic Blood Pressure Monitor, Model BP-3BTO-1, is as safe and effective as the predicate, the Microlife Automatic Blood Pressure Monitor, Model BP-2BHO based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 7 2002

Microlife Corporation
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K013485
Trade Name: Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1, with Optional Thermal Printer, Model PR 1KA1
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 17, 2001
Received: October 19, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K013485

Device Name: Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1, with Optional Thermal Printer, Model PR 1KA1

Indications For Use:

The Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1 with Optional Thermal Printer, Model PR 1KA1 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. This device can be used in connection with the Microlife Thermal Printer.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013485

Prescription Use ____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**